No. 1:17-md-02775

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

Phyliss Mosca v. Smith & Nephew, Inc., NO. 1:18-CV-3520

DEFENDANT SMITH & NEPHEW, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Smith & Nephew's Motion for Summary Judgment should be granted. Plaintiff has failed to meet her burden to demonstrate that there is any material issue of disputed fact, and the record "taken as a whole could not lead a rational trier of fact to find for [Plaintiff]." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

THE FACTS THAT MATTER ARE UNDISPUTED

In an effort to distract attention from the facts that are established by the record and relevant to Smith & Nephew's Motion, Plaintiff spins and distorts the truth, highlighting irrelevant materials to make it appear she has created a sufficient factual dispute to get some or all of her claims to a jury. She has not. Here are the actual, undisputed facts that matter:

- Dr. Boucher was trained on the BHR in England in 2006. He also attended a Smith & Nephew meeting in October 2007 (prior to the time when Plaintiff alleges Smith & Nephew knew of higher revision rates for female patients).[1] The meeting Dr. Boucher attended in 2009 in Baltimore was an independent course not put on by Smith & Nephew.[2]

- After his training, Dr. Boucher kept up on the BHR, including review of peer-reviewed literature, and attending conferences and professional meetings.[3]

- In making patient treatment decisions, Dr. Boucher relies on his training, peer-reviewed literature, and information from professional conferences and meetings he attends.[4]

- Dr. Boucher does not recall reading the BHR package insert.[5]

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[1] Boucher (Mosca) Dep. (Feb. 7, 2020) at 81-82 (Ex. A).

[2] *Id.* at 87-88; Expert Report of Dr. Michael A. Mont at 81-82 (Ex. F to Smith & Nephew's Memorandum in Support of Motion for Summary Judgment [D.E. 2518-1] ("SJ Mem.").

[3] Boucher (Mosca) Dep. at 90.

[4] *Id.* at 35, 37-38.

[5] *Id.* at 111-12.

- Dr. Boucher does not recall receipt of or whether he read the two Dear Doctor letters known to have been sent to him by Smith & Nephew prior to Ms. Mosca's implant in May 2010, specifically:
    - Dear Doctor Letter with Australian Registry 2007 Annual Report information relating to resurfacing results through December 2006.[6] (Plaintiffs do not rely on this, since it predates when they claim Smith & Nephew first knew of higher revision rates in female patients.)
    - Dear Doctor Letter finalized in January 2010 with Australian Registry 2009 Annual Report information relating to resurfacing results through December 2008 and focusing on males under 65 years old.[7]
- Dr. Boucher did not base his patient treatment decisions on Smith & Nephew's advertising.[8]
- Dr. Boucher was aware in May 2010 from the literature and conferences he attended that women had a greater risk of revision than men, and agreed there was a debate in the orthopedic community in 2010 and years following about the cause for that greater risk.[9]
    - Dr. Boucher never testified that he derived information solely from Smith & Nephew or that he based his decision to use the BHR on Ms. Mosca only on information from Smith & Nephew.
    - His sales representative never discussed Smith & Nephew's competitors with Dr. Boucher or shared any promotional materials with him.[10]
- Dr. Boucher was aware prior to May 2010 that the BHR could result in the release of metal ions, and that there was a risk of wear, loosening, pain and need for revision.[11]
- Dr. Boucher had more than one discussion with Ms. Mosca between 2007 and 2010, in which he informed her of the risks of a metal-on-metal bearing, including release

[6] Ex. 4 to Plaintiff's Mem. in Support of Motion for Summ. Judgment [D.E. 2514-1] ("Pltf. Mem.").

[7] Ex. 5 to Pltf. Mem.

[8] Boucher (Mosca) Dep. at 51.

[9] *Id*. at 193-94.

[10] Deposition of Terence Vincent Powers (Jan. 8, 2020) (Ex. B), at 230-33, 236-37, 240, 246-47.

[11] Boucher (Mosca) Dep. at 104-06, 112-15, 193-94; Boucher (Sedgwick) Dep. at 30 (Ex. D to SJ Mem.).

of metal ions, wear, loosening, pain and the need for revision.[12]

- Ms. Mosca does not recall being told of any of these risks, but does not dispute that she was informed of them.[13]

- Ms. Mosca never saw any BHR promotional materials, advertising, warranties, or other materials relating to the BHR, and was not relying on any representation Smith & Nephew made regarding the safety of the BHR prior to her implant surgery.[14]

- There is no evidence that Dr. Boucher ever discussed with Ms. Mosca the revision rate for the BHR or that women had a greater risk of revision then men.[15]

- Smith & Nephew received two ad hoc reports from the Australian Registry in October 2009, seven months prior to Ms. Mosca's implant surgery.

- Dr. Boucher did not testify that he would not have used the BHR on Ms. Mosca if he had known of the higher revision rates reflected in the October 2009 ad hoc registry reports. To the contrary, he stands by his decision to use the BHR on Ms. Mosca, who was only 44 years old at the time of her implant.[16]

In contrast, it is irrelevant whether Smith & Nephew "aggressively" promoted the BHR; whether Dr. Boucher's understanding that the BHR performed better than competitors or of the revision risks in May 2010 were "consistent with" information in Smith & Nephew materials he never saw or did not rely on; or whether an e-mail in March 2010 from Joseph DeVivo relating to marketing of the BHR was a threat to fire two employees (it was not). Ms. Mosca's litigation-driven statements that she would not have had the BHR if she had known about the potential for metal ion release or of higher revision rates in women should be excluded. *See* Smith & Nephew's

[12] July 24, 2007 Office Note (Ex. J to SJ Mem.); May 17, 2010 Operative Report (Ex. L to SJ Mem.); May 17, 2010 Informed Consent Form (Ex. M to SJ Mem.).

[13] Mosca Dep. at 150-56, 159 (Ex. B to SJ Mem.)

[14] *Id*. at 101, 148, 150, 178, 265-66 (Ex. B to SJ Mem.); Mosca Supplemental Responses to Smith & Nephew's First Set of Requests for Admission (Feb. 26, 2011), Nos. 38, 39, 41-44, 54 (Ex. N to SJ Mem.).

[15] *Id*., No. 38 at 11 (Ex. N to SJ Mem.); Mosca Dep. at 166-67 (Ex. B to SJ Mem.).

[16] Boucher (Mosca) Dep. at 145, 149-50 (Ex. A).

Mosca-Specific Motion *in Limine* No. 3 to Exclude Testimony, Other Evidence and Argument About What Plaintiff Would Have Done With Different Information [D.E. 2542].

Finally, Plaintiff cannot avoid summary judgment through reptilian tactics such as calling the 2009 *ad hoc* reports "secret" and Smith & Nephew's communications to doctors "off-label." The former is simply false and misleading; the latter is a term of art relating to use of a drug or device by physicians in a manner other than approved by FDA, which is inapplicable here.

I. SMITH & NEPHEW IS ENTITLED TO SUMMARY JUDGMENT ON MS. MOSCA'S BREACH OF WARRANTY CLAIM.

A. The Express Warranty Claim is Time-Barred.

Plaintiff's effort to avoid the four-year statute of limitations applicable to her breach of warranty claim by claiming that Smith & Nephew's warranty explicitly extended to future performance and thus falls within an exception to the rule is to no avail. Indeed, it fails on every level. Most prominently, Plaintiff fails to identify any statement by Smith & Nephew, written or oral, that promised any particular length of time that the BHR would last after implantation. That alone is fatal to her argument.

Rather, Plaintiff relies on testimony by Dr. Boucher that his general expectation as of 2010 was that "artificial hips" would last 15 years. Boucher (Mosca) Dep. at 165-66 (Ex. A). Dr. Boucher never testified that this "expectation" had been conveyed to him by Smith & Nephew, much less that his expectation derived from any particular statement that Smith & Nephew made to him.[17] Nor did Dr. Boucher testify that his understanding (as it existed in 2010) of revision rates

[17] Ironically, while claiming that Smith & Nephew's Dear Doctor letters provided only global revision rates and should have divulged sub-population-specific information, Plaintiff cites testimony from Smith & Nephew's expert Dr. Mont agreeing, in general, that a hip implant is "more likely than not" to last more than 25 years, without asking him to break this down by type of implant, much less by sub-population. Pltf. Mem. at 9 (citing Mont Dep. at 91, where he notes that while 58 percent of hip replacements in one study lasted 25 years, 42 percent did not).

came from Smith & Nephew. Dr. Boucher based his patient decisions on his practice experience, review of peer-reviewed literature and attendance at professional conferences and meetings. *Id*. at 35, 37-38. [18] Plaintiff glosses over this reality again and again, hoping the Court will not notice that there is no factual support for her broad brush claims, glossy interpretations of the actual facts, and loose associations between events that have no connection.

Among other sleight-of-hand, Plaintiff tries to conflate the general *impression* Dr. Boucher said he received in his training in 2006 that the BHR's performance was better than its competitors with a specific warranty of future performance. That effort also fails. Plaintiff's own expert concedes that the BHR's performance *was* better than its competitors. *See* Deposition of Jeffrey Shapiro, M.D. (Redick) (Jan. 26, 2021) at 319-20 (Ex. U to SJ Mem.) (when asked whether the BHR was "the best performing of the resurfacing devices," he said that the BHR's "numbers that were presented were *better than their competitors*" and that, relative to "other resurfacing devices," the BHR "was the best of the worst"); *see also* Shapiro Dep. (Sept. 11, 2020) (Ex. C) at 273 (testifying as general liability expert that his understanding, based on his own research, is that BHR has better outcomes than other resurfacing systems). And a general impression is a far cry from a specific guarantee of future performance. "The law is clear . . . that the future warranties exception applies only when the warrantor expressly warrants that the product will have a particular quality for a particular duration of time." *Brocious v. U.S. Steel Corp.*, 429 F. Supp. 3d 82 (D. Md. 2019). Here, no such warranty was made. A warranty that "simply states that the goods have a certain positive quality or are free from all or certain defects but states no time period during which the goods will continue to have that quality . . . does not reference or extend to any future

[18] Dr. Boucher also testified that he understands it is impossible to guarantee how long a device will last, and that he doesn't think he would have guaranteed any particular length of time to Ms. Mosca. Boucher (Mosca) Dep. at 67-68, 110-11 (Ex. A).

performance." *Joswick v. Chesapeake Mobile Homes, Inc.*, 362 Md. 261, 272 (2001). At most, Plaintiff's allegations rise to the level of a warranty that the BHR had a "certain positive quality" but that does not fall within the future-performance exception to the four-years-from-tender-of-delivery statute of limitations.

B. Ms. Mosca's Warranty Claim Fails Because She Never Saw or Heard Any Alleged Warranties.

As discussed in Smith & Nephew's Summary Judgment Memorandum ("SJ Mem.") at 12-15, Ms. Mosca's claim also fails because no warranties were ever made to Ms. Mosca by Smith & Nephew. Plaintiff complains that Smith & Nephew "misstates the Court's holding" in *Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.*, No. CCB-12-1746, 2013 WL 1104427 (D. Md. Mar. 13, 2013), but that is untrue. Smith & Nephew cited the case to support the assertion that Plaintiff has no breach of warranty claim because (1) Smith & Nephew owed no duty to provide information to her directly, as opposed to her surgeon who is a learned intermediary, and (2) "she concedes that she did not see, hear, or rely on any statements by Smith & Nephew regarding the BHR prior to implantation of the device, or, indeed, at any time. . . . Plaintiff cannot show that any statements by Smith & Nephew were part of the basis of the bargain or caused her injuries." SJ Mem. at 12-13.

Similarly, Smith & Nephew correctly cited the ruling in *Morris v. Biomet, Inc.*, No. GJH-18-2440, 2020 WL 5849482 (D. Md. Sept. 30, 2020), and explained why the facts here should lead to the same result. In *Morris*, Plaintiff's warranty claim failed because she did not see, hear or rely on any statements by the manufacturer that her implant was "pain-free." *Id.* at *12. Rather, she relied on the expertise of her doctor in choosing which device to implant, and the alleged statements never became a basis of the bargain." *Id.*; SJ Mem. at 13. The same is true here.

Plaintiff simply misrepresents the facts of her case in an effort to avoid the outcome in

Morris, which ended in summary judgment in favor of the manufacturer. But no matter how many times she repeats it, it simply is not true that Dr. Boucher repeated some unspecified warranty from Smith & Nephew to Ms. Mosca about how long the BHR would last or anything else. Plaintiff has created a house of cards based on the notion that what Dr. Boucher supposedly told Ms. Mosca was "consistent with" Smith & Nephew's advertising and statements in Dear Doctor Letters and during Dr. Boucher's training. But there is no evidence that Dr. Boucher told Ms. Mosca the BHR was better than its competitors, or about any particular revision rate at all,[19] and Dr. Boucher has made clear that his understanding of its performance was based on a broad array of information from multiple sources other than Smith & Nephew. Plaintiff has not alleged any facts that would justify sending this claim to a jury. Her breach of warranty claim should be dismissed.

II. PLAINTIFF'S NEGLIGENT MISREPRESENTATION CLAIM CANNOT SURVIVE SUMMARY JUDGMENT.

Plaintiff's looseness with the facts is matched by her discussion of the law. To begin with, Plaintiff mis-cites *Priv. Mortg. Inv. Servs. v. Hotel & Club Assocs., 29*6 F.3d 308, 315 (4th Cir. 2002), for the proposition that "[m]anufacturers that misrepresent the benefits and/or risks of a product are subject to liability for negligent misrepresentation." Pltf. Mem. at 12. But that case held, under South Carolina law, that a real estate appraiser who negligently appraises a property can be liable for negligent misrepresentation if the appraisal is detrimentally relied upon by a third party. The case does not involve a manufacturer at all, makes no broad statement about negligent misrepresentation claims, does not apply Maryland law, and thus is irrelevant to Plaintiff's claim.

[19] Plaintiff's assertion that "Ms Mosca understood that the BHR performed better than other metal-on-metal devices independent of gender or device size," and "that the BHR had low magnitude of risk of revision" (Pltf. Mem. at 11) tellingly cites to Dr. Boucher's Deposition (where he does not say this), not Ms. Mosca's. Nowhere in the record does Dr. Boucher say he told Ms. Mosca these things, and nowhere does she say that she understood them.

A. Plaintiff Cannot Show Justifiable Reliance or Causation.

Smith & Nephew has established that Plaintiff's negligent misrepresentation claim fails because she cannot show either justifiable reliance by Dr. Boucher or that any such justifiable reliance caused her injuries. SJ Mem. at 16-18. In response, Plaintiff tries to refute an argument Smith & Nephew never made through reliance on inapposite case law.

First, Plaintiff argues that Smith & Nephew cannot avoid liability to Ms. Mosca by invoking the learned intermediary doctrine to establish that Ms. Mosca did not justifiably rely on Smith & Nephew's alleged misrepresentations. Pltf. Mem. at 12-13. She cites cases such as *Christiansen v. Wright Med. Tech., Inc.*, 127 F. Supp. 3d 1306, 1362 (N.D. Ga. 2015), for the proposition that "justifiable reliance by the physician on misrepresentations or concealment by the manufacturer of that device constitutes justifiable reliance by the patient." But Smith & Nephew does not challenge that principle. Rather, Smith & Nephew correctly stated that, "Because the manufacturer's duty runs only to the physician in cases involving medical devices, the issue is whether the physician justifiably 'relied on the alleged misrepresentations.'" SJ Mem. at 16 (quoting *Kane v. Zimmer Biomet Holdings, Inc.*, No. RDB-17-2268, 2018 WL 4005216, at *5 (D. Md. Aug. 22, 2018)). Smith & Nephew then went on to show that *Dr. Boucher did not justifiably rely* on any alleged misrepresentations by Smith & Nephew in making his decision to use the BHR on Ms. Mosca. *Id.* at *16-18. Since Dr. Boucher did not justifiably rely on any alleged misrepresentations by Smith & Nephew, Plaintiff cannot recover. In this important respect, Ms. Mosca's case is most similar to *Morris*, 2020 WL 5849482, at *10-11 (dismissing misrepresentation claim because there was "no evidence" the surgeon relied on alleged misrepresentations; rather he relied on his training, experience and analysis of peer-reviewed medical literature").

In all other respects, *Christiansen* is inapposite, and Plaintiff is mistaken in arguing that it is more similar to Ms. Mosca's case than *Morris*. To the contrary, *Christiansen* is distinguishable on a variety of fronts. Most prominently, it did not involve a PMA-approved device, so the Court ruled that preemption was inapplicable to bar any of Plaintiffs' claims based on strict liability, negligence and alleged fraud. 127 F. Supp. 3d at 1355-56. The Court granted summary judgment on Plaintiff's failure to warn claim under Utah law because the surgeon did not read the package insert. *Id*. at 1359-61. The same is true here (Dr. Boucher did not read the package insert), though in Ms. Mosca's case, the Court has dismissed the failure-to-warn-the-medical-community claim as preempted.[20]

Most critically, in *Christiansen*, the surgeon testified that "the information he had about the product came primarily from [defendant's] representatives." *Id*. at 1360. That is in stark contrast to Dr. Boucher, who was trained by Smith & Nephew on the BHR in 2006 and attended a course in 2007 – prior to the time Plaintiffs allege Smith & Nephew had any information about higher revision rates in females and small head sizes; did not receive any information from any sales representatives on these issues;[21] and relied for his decision to use the BHR on his own patient experience, review of peer-reviewed literature, and attendance at professional meetings and courses, including independent courses such as the one he attended in 2009. Boucher (Mosca) Dep. at 35, 37-38. Unlike *Christiansen*, the information he had about the product did not come primarily

[20] Notwithstanding dismissal of her failure to warn the medical community claim as preempted, Plaintiff persists in arguing that Smith & Nephew had a duty to warn Dr. Boucher about the data in the 2009 ad hoc registry reports. Smith & Nephew regrets that this litigation is turning into something akin to a game of whack-a-mole, but asks the Court again to rebuke this misguided effort to keep dismissed claims alive by slightly altering their description or rationale.

[21] Powers Dep. at 230-33, 236-37, 240, 246-47 (Ex. B).

from Smith & Nephew's representatives.[22]

Contrary to Plaintiff's assertion, *Christiansen* does not stand for the general proposition that "reliance is a question for the jury in the metal hip context." Pltf. Mem. as 12. Rather, the Court simply found that plaintiff had demonstrated reliance by the surgeon on the defendant's representations (not true here), and that this, combined with plaintiff's allegations about defendant's knowledge and conduct, raised a genuine issue of material fact that must be decided by the jury. 127 F. Supp. 3d at 1364. In arguing for a similar result here despite the different facts, Plaintiff also relies on documents not seen by Dr. Boucher (*e.g.*, Pltf. Mem. at 14 and Exs. 20-22 to Pltf. Mem.) that, in any event, predate the October 2009 ad hoc reports.[23]

B. There is No Proof of Any False Statements of Fact.

Plaintiff does not identify any statement of fact made by Smith & Nephew that was false. Instead, Plaintiff conflates time periods, mixing the period when Dr. Boucher was trained in 2006 with the time period between October 2009 and May 2010 when Smith & Nephew had the allegedly "secret" data in the two ad hoc Australian Registry reports. *See* Pltf. Mem. at 15-16

[22] The best Plaintiff can do is to argue that Dr. Boucher learned in 2006 at his training that the BHR's performance was better than that of its competitors, and that this had something to do with its as-cast (vs. heat-treated) manufacturing method. But Plaintiff's own expert agrees Smith & Nephew's performance was better than its competitors, so this was a true statement, and the reasons for it are irrelevant (and not even well-understood by Dr. Boucher, much less relied upon by him). *See* Boucher (Mosca) Dep. at 154-55 (Ex. A).

[23] Similarly, *McCoy v. Biomet Orthopedics, L.L.C.*, No. ELH-12-1436, 2021 WL 252556 (D. Md. Jan. 25, 2021) does not stand for the general proposition that " it is the probability and magnitude of the risk of revision – not simply listing what the risks are – that is the appropriate framework, and question for the jury, in a metal on metal hip case." Pltf. Mem. at 14. In *McCoy*, the court declined to rule *as a matter of law* that the warnings in the product labeling were adequate, where plaintiff's expert opined that they "understated the probability or magnitude" of the adverse effects, and thus the court denied summary judgment on plaintiffs' strict liability and negligent failure to warn claims. 2021 WL 252556, at *27. Here, by contrast, the Court has dismissed as preempted plaintiff's strict liability and failure to warn the medical community claims, and the PMA-approved labeling is not at issue.

(arguing that "Smith & Nephew's secret data showed that the risk of revision to women and smaller device sizes was actually 3-4 times higher…").[24] Plaintiff essentially contends that Smith & Nephew had an ongoing duty to update its surgeon training as soon as new information about the BHR was received. But the Court has rejected any duty to update surgeon training. *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig*., 2021 WL 781682, at *90-91 (D. Md. Mar. 1, 2021) ("Daubert Ruling"). The training that Smith & Nephew provided Dr. Boucher in 2006 was truthful and consistent with the FDA-approved labeling, and Plaintiff does not contend otherwise. Similarly, Plaintiff points to nothing in the two Dear Doctor letters sent to Dr. Boucher prior to May 2010 that she contends is false.

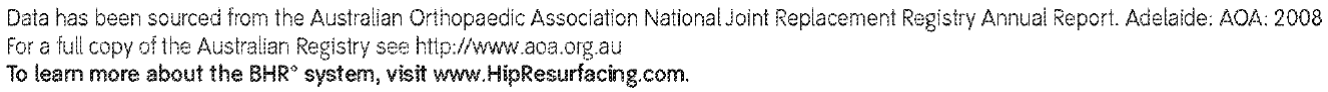
Rather, her claim amounts to an insupportable argument that if Smith & Nephew provided any information at all to doctors about the BHR outside of the labeling, such as global revision rates for all populations, or revision rates relating to one particular sub-population (such as males under age 65), it had a further obligation to provide all other sub-population data it had received as of that date. There is nothing in the law that would require that.[25] And it ignores the sophisticated

[24] Even Plaintiff's own expert, Dr. Shapiro, does not opine that Smith & Nephew had a duty to provide every report to surgeons. Shapiro Dep. (Feb. 3, 2021) at 83-84 (Ex. D) ("I don't think every time a report comes out, they have to send out a copy of the report to everybody . . . ."). And this Court has dismissed any claim that Smith & Nephew had a duty to provide information to the medical community.

[25] The case law Plaintiff discusses relating to whether an assumption of a duty can occur in various contexts under Maryland law is largely inapposite or misrepresented. *See, e.g.*, C*hassels v. Krepps*, 235 Md. App. 1, 11 (2017) (overturning lower court decision dismissing claim without leave to amend and stating that the father should at least have an opportunity to try to adequately allege a duty to the child, though "[i]t's not obvious he can state a claim"); *Krieger v. J.E. Greiner Co.*, 282 Md. 50, 70 (1978) (overturning demurrer and stating that plaintiffs should have an opportunity to amend "to allege – if they have a proper foundation for such an allegation – some other possible hypothesis for recovery" based on a theory of assumed responsibilities). And *W. Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc., 57* F. Supp. 3d 950, 969-73 (D. Minn. 2014) is a securities class action, where the court found that in the specific context of the statute at issue that statements in SEC filings were non-actionable puffery that investors would not plausibly rely upon.

surgeon audience to whom these communications were directed. Dr. Boucher surely had the education and experience to understand that total population data might not be identical to sub-population data. Nor can Plaintiff credibly claim that Dr. Boucher did not understand that scientific knowledge changes over time, and that the information he was provided in 2006 might be subject to revision based on new data as the BHR continued to be used over time. That is why he based his patient decisions on his own practice experience, review of the peer-reviewed literature, and what he learned during attendance at professional meetings. Boucher (Mosca) Dep. at 35, 37-38 (Ex. A). He did not rely on Smith & Nephew as his sole source of information.

Plaintiff's attempt to squeeze into the narrow exception under which a negligent omission could be actionable under Maryland law is to no avail. This is not a case where Smith & Nephew "affirmatively represent[ed] only a fragment of the entire picture." *Kiddie Acad. Dom. Franchising, L.L.C. v. Wonder World Learning, L.L.C.*, No. ELH-17-3420, 2020 WL 4338891, at *24 (D. Md. July 27, 2020). Quite the contrary. Here, Smith & Nephew gave the full picture – the global revision rates. Smith & Nephew did not obscure the sub-population data by doing so, but, instead, repeatedly invited surgeons to view the entire Registry, including in its Dear Doctor letter that focused on resurfacing performance in males under age 65:


Data has been sourced from the Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide: AOA: 2008
For a full copy of the Australian Registry see http://www.aoa.org.au
To learn more about the BHR® system, visit www.HipResurfacing.com.

Ex. 5 to Pltf, Mem. at SN_BHR_MDL_075971.[26] Any surgeon who wanted particular sub-

[26] Plaintiff takes the testimony of Smith & Nephew corporate representative Blair Fraser out of context and misrepresents it as corporate testimony when in fact, it was outside the scope of the Rule 30(b)(6) topics he was presented to address. *E.g.*, Fraser Dep. at 182 (objecting to scope) (Ex. 16 to Pltf. Mem.). Mr. Fraser did not say or suggest that Smith & Nephew intentionally highlighted global revision rates in publications to hide data involving certain sub-populations, as Plaintiff suggests. Pltf. Mem. at 6. To the contrary, in discussing an internal Health Hazard Evaluation ("HHE") prepared by the company *in 2015*–years after Plaintiff's implant surgery–Mr. Fraser explained that the company carefully reviewed sub-population performance data "in a stratified

population data could simply ask for it and obtain it for free. *See* Peter Heeckt Dep. (Dec. 1, 2020) (Ex. E), at 139-40 ("Surgeons were always free to ask the registry certain questions if they wanted to, even free of charge.").

Indeed, similar information was being discussed publicly in the literature and professional societies that Dr. Boucher reviewed and relied upon. *See* Boucher (Steinwandt) Dep. (June 26, 2020) at 57 (Ex. F) (testifying that he uses online medical databases to obtain information relevant to his practice from the Hip and Knee Society and the American Academy of Orthopedic Surgeons("AAOS")). For example, the AAOS in February 2010 announced that it was establishing a new technology overview on hip resurfacing and identified "[s]ubgroup analyses of interest that require further investigation," including gender, age and component size.[27] As for gender-related differences, AAOS said, "The most recent registry reports differ on whether women are at greater risk for revision than men after HR or after THA. *Two registries find no gender-related difference; the third registry finds that women who received HR and men who received THA were at greater risk for revision." Id.* (emphasis added). It also stated that "[s]maller components are at greater risk of revision than larger ones." *Id*.

This is consistent with Dr. Boucher's understanding that there was ongoing debate in the orthopedic community about the reasons for gender differences. And it shows that one registry

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manner as [much as] we possibly could to find out which patient subpopulations were most at risk, and in whom the device performs well [and] may be of significant clinical benefit to those patients. . . ." Fraser Dep. at 182. Plaintiff's counsel suggested that the HHE should have included a table for the "overall rate" and that "if you're starting a process to figure out whether or not you should leave a product on the market, what makes the most sense to look at is the overall revision rate." *Id*. at 181, 183. Mr. Fraser explained that the company knew the BHR was performing well overall, but needed to understand "whether there were any masked or camouflaged patient populations within the overall BHR cohort . . . so that we could take the appropriate action in the interest of patient safety." *Id*. at 183.

[27] *See* https://www.aaos.org/aaosnow/issue/?issue=AAOSNow/2010/Feb (full article attached as Ex. G).

does not always agree with another, which is why Smith & Nephew needed to analyze the data received from the Australian registry, compare it to other sources and try to understand what it signaled, if anything. *See also* Boucher (Mosca) Dep. at 145-47 (Ex. A) (acknowledging limitations of registry data and the need to investigate it further before drawing conclusions). Plaintiff's assertion that a "true revision risk" existed in the period between October 2009 and May 2010 that was known only to Smith & Nephew based on the two ad hoc Australian Registry reports from October 2009 is simply fiction.

Similarly, an article published in April 2010 in the British version of the Journal of Bone and Joint Surgery (which Dr. Boucher followed)[28] titled, "The influence of the size of the component on the outcome of resurfacing arthroplasty of the hip: a review of the literature" canvassed the literature to identify possible reasons for resurfacing failures, citing the most common as "fracture of the femoral neck, loosening of the component, osteonecrosis of the femoral head, reaction to metal debris and malpositioning of the component." *See* Ex. H (abstract). Another article in January 2010 in the same journal "sought to establish the rate of failure secondary to adverse reactions to metal debris (ARMD) in our patients, to identify relationships between this mode of failure and the wear rate of the prosthetic joint, and to provide a potential explanation for the increased incidence of this in women." *See* Ex. I.

And in January 2010, McBryde, et al. published an article in the same journal titled "The Influence of Head Size and Sex on the Outcome of Birmingham Hip Resurfacing." *See* Ex. J. This article was supplied by Smith & Nephew to FDA with its 2010 Annual Report, but was publicly available and indicated that while "[t]he five-year cumulative survival rate for the 655 hips that were followed for a minimum of five years was 97.5%. . . . Revision was significantly associated

[28] Boucher (Mosca) Dep. at 37 (Ex. A).

with female sex . . . and decreasing femoral component size. . . ." *Id*. at 1 (Results). Dr. Boucher was shown the McBryde article during his deposition and testified that he didn't remember reading it, but he "may have" and that the JBJS is something he "would have typically kept up with." Boucher (Mosca) Dep., at 92-93 (Ex. A). This puts the lie to Plaintiff's contention that Smith & Nephew told Dr. Boucher that any differences in performance were due solely to femoral neck fractures, and he had no other source of information to indicate otherwise. The literature in the period prior to Ms. Mosca's surgery was more than adequate to inform Dr. Boucher about the variables that might affect revision rate, and he testified that he followed this literature and relied on it to make patient treatment decisions.[29] Plaintiff would have the Court believe in an alternative universe where Dr. Boucher had no information other than what Smith & Nephew told him, but that universe simply does not exist.

C. Smith & Nephew Had No Duty to Supply the Ad Hoc Reports to FDA and Even if it Had Provided Them to FDA, It Could Not Have Changed Ms. Mosca's Outcome.

In its opposition to Plaintiff's Summary Judgment Motion, Smith & Nephew debunks Plaintiff's untrue assertion that its expert Dr. Donna-Bea Tillman admitted Smith & Nephew had a legal duty under its PMA to turn the 2009 ad hoc Australian Registry reports over to FDA as soon as it received them. [D.E. 2594 at 14-17]. But even if Smith & Nephew had voluntarily provided copies of the two reports to FDA or otherwise advised FDA of their contents in October

[29] Plaintiff also asserts that Dr. Boucher's belief in 2010 that the BHR revision rate was 1-3 percent came from Smith & Nephew. In support, she holds out a PowerPoint presentation by a Smith & Nephew employee from 2008 on Femoral Neck Fracture in Hip Resurfacing, which there is no evidence Dr. Boucher ever saw, as evidence that Smith & Nephew "obscured the magnitude of the risk of revision." But she fails to note that the presentation cites the "current revision incidence" as approximately 4.6%. Ex. 32 to Pltf. Mem. at SN_BHR_MDL_1277501. Further, there is no evidence that the *reason* for any difference in revision rates by gender was significant to Dr. Boucher's decision to use the BHR for Ms. Mosca.

2009, there is no causal path that would change Ms. Mosca's outcome. Faced with her own admission that she cannot show what FDA would have done even if the ad hoc reports had been provided, Ms. Mosca now pivots to an alternative assertion that providing this data to the FDA would have made it "public" and that Dr. Boucher would have seen it. Pltf. Mem. at 26. Specifically, she suggests it would have been made public either through the MAUDE database or if "Smith & Nephew include[ed] it in voluntary, extra-labeling statements that the company made in order to insure those statements [sic] truthful and not misleading. . . ." Pltf. Mem. at 27. This causation theory fares no better than the others.

First, Plaintiff's alternative scenario whereby Smith & Nephew advised Dr. Boucher directly about the ad hoc Australian Registry data is nothing other than her repeated contention that Smith & Nephew had a duty to warn Dr. Boucher of all information it had on revision rates whenever it obtained the data. No such duty existed, and the Court has explained that any claim to the contrary is preempted. That leaves her theory that the FDA would have made the Registry data public by placing it on the MAUDE database. But Plaintiff expressly has disavowed any argument that FDA would have done something different if provided with additional information. *Daubert* Ruling, 2021 WL 781682, at *5 n.1 and *13. Further, Smith & Nephew had no obligation to report registry data as an MDR to the MAUDE database.[30] Indeed, the registry data are aggregated and nonspecific to any particular medical event, whereas MDRs are intended to identify particular

[30] Plaintiff's regulatory expert Larry Spears did not opine that Smith & Nephew was required to provide the ad hoc reports themselves to FDA, only that the revision rates in them should have been communicated to FDA. Spears Dep. (Sept. 9, 2020) at 33 (Ex. K) ("I'm not saying they need to necessarily send their report. I'm not saying how they need to provide it. . . . There's lots of ways to communicate."). Further, Mr. Spears never opined that the registry reports themselves should or could have been submitted to the MAUDE database. And he could not rule out that any revisions reflected in the ad hoc reports that had come to Smith & Nephew's attention through other means had, in fact, been reported as MDRs to the MAUDE database. *Id*. at 57-58.

events involving individuals. And Dr. Boucher testified that he did not make it a practice to review the MAUDE database in any event. Boucher (Mosca) Dep. at 199 (Ex. A). Plaintiff is thus left with speculation that (i) if the October 2009 ad hoc Registry reports were somehow placed in the MAUDE database, (ii) someone would have picked up on it and (iii) published an article by no later than early May 2010 that (iv) would have been seen by Dr. Boucher and (v) would have changed his decision to use the BHR on Ms. Mosca.[31] Implausible speculation cannot carry her over the causation bar.

Plaintiff's reliance on *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011), is misplaced. The Fifth Circuit did not address whether plaintiff failed to present enough evidence to create a genuine issue of material fact because the lower Court had found plaintiff's failure to warn claim preempted, and thus had not considered the causation issue in the first instance. *Id.* at 776 (remanding case to address causation). And there, the plaintiff alleged not only that defendant failed to submit reports of burns caused by leaks from its device as MDRs to FDA, but that FDA had itself found fault with the algorithm defendant used to determine which burn incidents were reportable. *Hughes* has nothing to do with aggregate data such as registry reports, and the footnote plaintiff cites (Pltf. Mem. at 26) is merely a recitation of plaintiff's causation theory that the court declined to address. It does not support her claims.

The same is true of *De La Paz v. Bayer HealthCare, LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016). In that decision, the Court dismissed plaintiff's failure-to-warn-the-FDA claim because "she has pled no facts that plausibly indicate that she or her physician would have become aware

[31] After earlier arguing that Dr. Boucher was entirely reliant on Smith & Nephew to provide the true information about BHR performance and revision rates, Plaintiff pivots to arguing that he was well-versed in the literature and would have seen and acted on any published articles that made use of the ad hoc Registry data. Plaintiff cannot have it both ways.

of [eight unreported] adverse events if Bayer had timely reported them to the FDA." *Id*. at 1097. Again, the reports that were allegedly not reported related to individual incidents, not aggregate registry-type data. Because Plaintiff has failed to show that Smith & Nephew had an obligation to report the Registry data to FDA, and that if it had, the data would have been seen and changed Dr. Boucher's decision to use the BHR on Ms. Mosca, her failure-to-warn-FDA claim should be dismissed.

III. PLAINTIFF'S NEGLIGENCE CLAIM FAILS.

Plaintiff protests that her negligence claim is not limited to surgeon training, but also includes negligence per se. Under whatever umbrella, Smith & Nephew has shown that both claims fail. Plaintiff's discussion of her surgeon training claim only confirms this. First, Plaintiff states that "Smith & Nephew's training actually included – pursuant to FDA requirements – delivering warnings about the risks of revision of the BHR." Pltf. Mem. at 30. Presumably, she refers to a memo in November 2007 (*after* Dr. Boucher was trained) regarding training of "core surgeons" that was to include "Anticipated PMA approved indications, contraindictions, warnings, and precautions. . . ." Ex. 28 to Pltf. Mem. at SN_BHR_MDL_1764969. Smith & Nephew trained surgeons in accordance with the applicable labeling. Plaintiff claims this training "was where Smith & Nephew disseminated information to Dr. Boucher at [sic] the low revision risk of 1-3%. . . ." Pltf. Mem. at 30. But even if subsequent data reflected higher revision rates, this Court has ruled that any claim that Smith & Nephew had a duty to update its training is preempted. 2021 WL 781682, at *8. And the only other "training" Plaintiff relies on is the September 2009 Mont conference that took place a month or more before Smith & Nephew first received the ad hoc registry reports. Smith & Nephew cannot be held liable for failure to train Dr. Boucher at a course Smith & Nephew did not hold, nor is the company responsible for any information disseminated

there (or not disseminated there) by Derek McMinn or Ronan Treacy, who were not its employees and were not appearing to speak for Smith & Nephew.[32] The negligence claim should be dismissed.

IV. PLAINTIFF'S PUNITIVE DAMAGES REQUEST SHOULD BE DISMISSED.

Smith & Nephew relies on its discussion of this issue in its Summary Judgment Memorandum and in its Opposition to Plaintiff's Motion for Summary Judgment, incorporated herein by reference. Plaintiff's claim rests on the ad hoc Australian Registry data and the seven months between October 2009 and May 2010, but there is no set of facts or theory of law that could get a claim for punitive damages to the jury based on Smith & Nephew's failure to provide that data either to Dr. Boucher directly or to FDA. Plaintiff has zero evidence of "evil motive," "intent to defraud" (there is no fraud claim here) or "intent to injure." Pltf. Mem. at 32.[33] The Court should grant summary judgment on Plaintiff's punitive damages request.

CONCLUSION

For all the reasons set forth above and in Smith & Nephew's Summary Judgment Memorandum, Smith & Nephew respectfully requests that its Motion be granted, and Ms. Mosca's case dismissed in its entirety.

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[32] Plaintiff points to a post-hoc Smith & Nephew summary of the Mont course (Ex. 2 to Pltf. Mem.), but offers no evidence that Dr. Boucher ever saw it.

[33] Plaintiff likes to bandy about the term "cash cow" but if keeping an eye on monetary matters is the same as an "evil motive," every corporation in the world is evil. Plaintiff also ignores the testimony showing that Smith & Nephew took this term from Boston Consulting Group, and it was meant to designate a program that does not require significant investment. "So the context here was BHR continues to remain on the market but not to have a large investment to do any development of that in terms of innovation." Dep. of Timothy Band (July 9, 2019), at 174-76 (Ex. K); *see also* Dep. of David Telling (Jan. 15, 2020), at 109 ("Milk as 'cash cow'" means "[n]o further investment") (Ex. L).

Dated: April 9, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of April 2021, a copy of the foregoing was filed via ECF and thereby served on all counsel of record.

/s/ Terri S. Reiskin